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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket No. 2002N-0370]

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Certifier D. Hawkins

**Neurological Devices; Classification of Human Dura Mater**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is classifying human dura mater intended to repair defects in human dura mater into class II (special controls). This action is being taken to establish sufficient regulatory control to provide reasonable assurance of the safety and effectiveness of the device. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a guidance document entitled "Class II Special Controls Guidance Document: Human Dura Mater" that will serve as the special control for this device.

**DATES:** This rule is effective *[insert date 30 days after date of publication in the Federal Register]*.

**FOR FURTHER INFORMATION CONTACT:** Charles N. Durfor, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-3090.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of October 22, 2002 (67 FR 64835), FDA issued a proposed rule to classify human dura mater into class II based on new

information regarding this device and the recommendation of the Neurological Devices Panel. FDA identified the draft guidance document entitled “Class II Special Controls Guidance Document: Human Dura Mater; Guidance for Industry and FDA” as the proposed special control capable of providing reasonable assurance of the safety and effectiveness of the device. The device is intended to repair defects in human dura mater. FDA invited interested persons to comment on the proposed rule by January 21, 2003. FDA received one comment.

## **II. Summary of the Comment and FDA’s Response**

The comment did not express an opinion on the proposed rule. It informed FDA of new research in transgenic mice which suggests that it may be difficult to distinguish whether a patient’s cause of death is related to Creutzfeldt-Jakob Disease (CJD) or variant CJD based on neuropathology. FDA appreciates receipt of the information but does not believe it affects the classification of human dura mater. The guidance document “Class II Special Controls Guidance Document: Human Dura Mater” recommends clinical and histopathological methods, including next of kin interviews and full brain autopsy, respectively, that are intended to identify and defer potential human dura mater donors who have either CJD or variant CJD.

## **III. FDA’s Conclusion**

Based on a review of the available information in the preamble to the proposed rule and placed on file in FDA’s Division of Dockets Management (HFA-305), Food and Drug Administration, 5600 Fishers Lane, rm. 1061, Rockville, MD 20852, FDA concludes that special controls, in conjunction with general controls, provide reasonable assurance of the safety and effectiveness of this device. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the class II special controls guidance document.

Following the effective date of this final classification rule, any firm submitting a premarket notification (510(k)) for human dura mater will need to address the issues covered in the class II special control guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

FDA is now codifying the classification and the class II special control guidance document for human dura mater by adding § 882.5975 to the device regulations in Title 21, Code of Federal Regulations (21 CFR). For the convenience of the reader, FDA is also adding § 882.1(e) to inform the reader where to find guidance documents referenced in 21 CFR part 882.

As discussed in the preamble to the proposed rule (67 FR 64835), FDA intends to transfer the regulation of human dura mater from the Center for Devices and Radiological Health to the Center for Biologics Evaluation and Research. FDA expects this transfer will take place upon the implementation of human-cellular and tissue-based product regulations, including regulations addressing donor suitability, good tissue practices, and registration and listing. FDA has initiated rulemaking proceedings involving these products. (See 64 FR 52696, September 30, 1999; 66 FR 1507, January 8, 2001; and 66 FR 5447, January 19, 2001.) In the interim, FDA believes that regulation of dura mater as a class II device subject to general and special controls provides a reasonable assurance of its safety and effectiveness.

#### **IV. Environmental Impact**

The agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on

the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

## **V. Analysis of Impacts**

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the final rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

FDA has also examined the impact of the rule under the Regulatory Flexibility Act. The purpose of this rule is to change the classification of human dura mater from an unclassified medical device into a class II medical device subject to special controls. As an unclassified device, this device is already subject to premarket notification and the general labeling provisions of the act. There are currently five to seven manufacturers of human dura mater medical devices. All of the firms meet the Small Business Administration's definition of a small entity (fewer than 500 employees). FDA, however, believes that manufacturers presently marketing this device already conform with many of the recommendations in the special controls guidance document. New manufacturers of human dura mater will only need to submit 510(k)s, as the statute now requires them to do, and demonstrate that they meet the

recommendations of the guidance or in some way provide equivalent assurances of safety and effectiveness. In addition, biocompatibility and structural testing recommendations are eliminated from the guidance, which will decrease the premarket notification costs for manufacturers introducing new human dura mater devices into commercial distribution. The agency, therefore, certifies that this rule will not have a significant economic impact on a substantial number of small entities. In addition, this rule will not impose costs of \$100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and therefore, a summary statement or analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

## **VI. Federalism**

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

## **VII. Paperwork Reduction Act of 1995**

This final rule does not contain information collection provisions that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

## List of Subjects in 21 CFR Part 882

Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 882 is amended as follows:

### **PART 882—NEUROLOGICAL DEVICES**

■ 1. The authority citation for 21 CFR part 882 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Section 882.1 is amended by adding paragraph (e) to read as follows:

#### **§ 882.1 Scope.**

\* \* \* \* \*

(e) Guidance documents referenced in this part are available on the Internet at *<http://www.fda.gov/cdrh/guidance.html>*.

■ 3. Section 882.5975 is added to subpart F to read as follows:

#### **§ 882.5975 Human dura mater.**

(a) *Identification.* Human dura mater is human pachymeninx tissue intended to repair defects in human dura mater.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled “Class II Special Controls Guidance Document: Human Dura Mater.” See § 882.1(e) for the availability of this guidance.

Dated: 12/5/03

December 5, 2003.

Linda S. Kahan

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